

REMARKS

I. STATUS OF CLAIMS

Claims 1-6 and 15-20 are pending and subject to examination. No claim is amended in this response.

II. REJECTIONS UNDER 35 U.S.C. § 103

A. Claims 1, 2, 4, 6 and 15-20

The Examiner rejects claims 1, 2, 4, 6 and 15-20 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,910,154 to Tsugita et al. ("Tsugita") in view of U.S. Patent No. 5,885,381 to Mitose et al. Office Action, pages 3-4. Again, the Examiner asserts that Tsugita "discloses the invention substantially as claimed, including a 'self-expanding strut assembly' (54) including a nickel-titanium alloy" (citing col. 8, lines 48-50) and "a 'filter element' (60) disposed on the strut assembly" (citing Figures 6A and 6B). *Id.* at page 3. However, the Examiner admits that Tsugita "does not disclose the superelastic alloy includes a ternary element." *Id.*

To remedy this deficiency, the Examiner relies on Mitose. The Examiner asserts that Mitose "teaches a superelastic alloy can have a ternary element to reduce the stress hysteresis and improve hot workability in the device (citing col. 3, lines 51-56) as compared to a simple nickel titanium alloy without a ternary element (citing figures 2 and 4)." *Id.* Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the nickel-titanium strut assembly of Tsugita reference with the alloy of Mitose having a ternary element (palladium) to reduce the stress hysteresis and improve hot workability in the

device. *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

In making a rejection under 35 U.S.C. § 103, the Examiner has the initial burden to establish a *prima facie* case of obviousness. See M.P.E.P. § 2143. In its recent decision in *KSR Internat'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385 (2007), the Supreme Court confirmed that the “framework for applying the statutory language of §103” was still based on its landmark decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). Under *Graham*, there are four factors for consideration when determining whether an invention is obvious:

- (1) the scope and content of the prior art;
- (2) the differences between the prior art and the claims at issue;
- (3) the level of ordinary skill in the art; and
- (4) secondary considerations.

Furthermore, an invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 127 S. Ct at 1741, 82 U.S.P.Q. 2d at 1396. While there is not a rigid rule requiring application of the “teaching, suggestion, or motivation” test, it can provide helpful insight in determining whether the claimed subject matter is obvious. See *id.* In the analysis supporting the rejection, “the apparent reason to combine known elements in the fashion claimed by the patent at issue . . . should be made explicit.” *Id.* (citing *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q. 2d 1329, 1336 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead,

there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)).

Additionally, following the *KSR* decision, the Office issued a memorandum to its technology center directors on May 3, 2007, indicating that “in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.” (emphasis in original).

As detailed below, it is evident that the Examiner has not established a *prima facie* case of obviousness even in light of the *KSR* decision. Specifically, the Examiner has failed to show that the alloys disclosed in the cited references exhibits a decreased stress hysteresis **due to a lowered loading plateau stress**, as claimed. In fact the Examiner cannot show this because the references, namely Mitose, desire just the opposite.

Conventional efforts of using a superelastic materials in medical device applications, such as stents and embolic filters, have focused only on a wider hysteresis in the stress-strain behavior in a loading or unloading cycle of the device. In terms of a stent, the wide hysteresis means that the inward force required to compress the stent transversely once in place in the lumen is relatively high, while the outward force that the stent exerts on the lumen as it attempts to revert to its original undeformed configuration is relatively low. This can mean that the lumen will be resistant to being crushed by externally applied forces which can be a problem in the case of lumens close to the surface such as arteries in the thigh and neck.

The same is true for orthodontic wires whose intent is to move teeth. In fact, Mitose expressly teaches that it is desired that a certain amount of tensile force be applied in working (loading) to attach the wire to the teeth, and that “a tensile force should be **as high as possible in unloading** to move the teeth after attaching the wire to the teeth, namely, the stress hysteresis should be small.” Col. 5, lines 25-28. (Emphasis added).

That hysteresis is defined by the difference between the loading and unloading plateau stresses of the material as plotted on a stress-strain curve. To illustrate the difference of the present invention in comparison with the prior art as discussed above and for the Examiner's convenience, Applicants respectfully submit the following three figures.

Figure 1 represents a typical stress-strain hysteresis.

Figure 2 represent the mechanism by which Mitose achieves a smaller hysteresis. As discussed in Mitose at col. 5, lines 25-28, and as indicated by the upward arrow, a smaller hysteresis is a result of a higher unloading plateau stress.

Figure 3 is an illustrative superelastic stress-strain curve according to the present invention in comparison with the standard superelastic NiTi. This Figure shows a downward arrow indicating a smaller hysteresis is a result of a lower loading plateau stress.

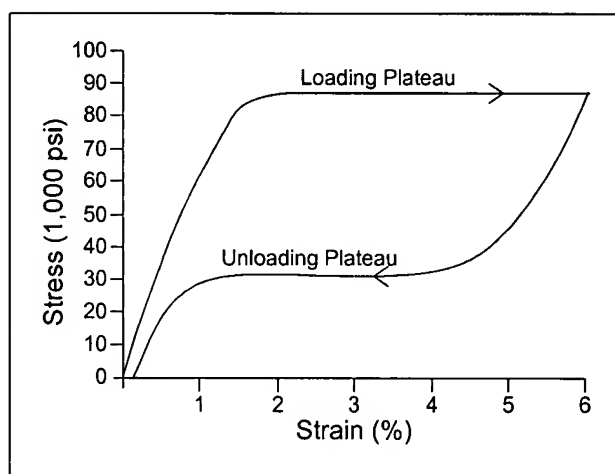


Figure 1: Typical Stress-Strain curve for superelastic NiTi.

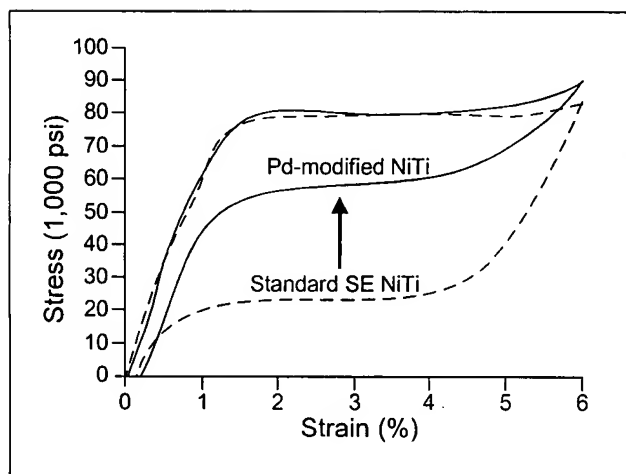


Figure 2: Superelastic stress-strain curve described in Mitose.

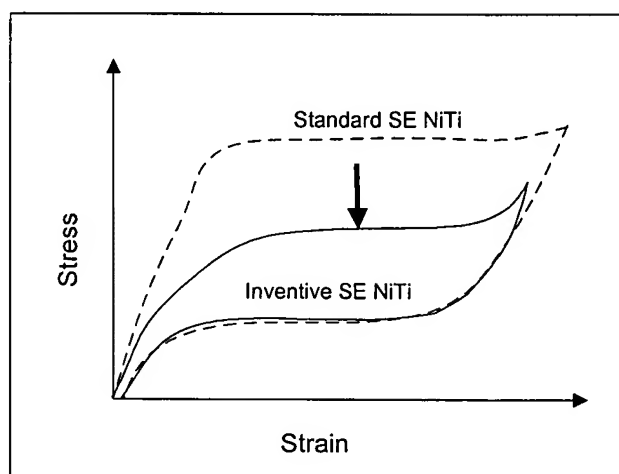


Figure 3: Illustrative superelastic stress-strain curve according to the present invention.

The graphical representation mentioned above is not only taught in Mitose, but it is specifically exemplified. As shown, in col. 7, lines 35-40, the inventive alloys of Mitose (1-8) achieved desired properties over the closest comparative examples 9 and 10, which contain Pd, like Examples 1-8, by increasing the unloading stress.

Thus, even if the intent of Mitose (to achieve a lower stress hysteresis by adding a ternary element) is the same as the claimed invention, the means by which it is achieved is completely opposite to the claimed invention. Therefore, the Examiner has failed to show that the alloy of Tsugita, alone or in view of Mitose, achieves a decreased stress hysteresis by decreasing the loading plateau stress, as claimed.

In order to satisfy the initial burden of establishing a *prima facie* case of obviousness, the Examiner must first show that the prior art references teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Examiner must also show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998). The suggestion or motivation "must be found in the prior art reference, not in the Applicants' disclosure." *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Nothing of record, other the Applicants' disclosure, teaches obtaining a decreased stress hysteresis by decreasing the loading plateau stress, as claimed. In fact, this rejection is fatally flawed since it relies on a reference that clearly teaches away from the claimed invention. See, *In re Laskowski*, 10 USPQ 2d 1397 (Fed. Cir. 1989).

The Examiner's attention is further directed to well-known Federal Circuit decisions holding that if a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See, *In re*

Fritch, 972 F.2d 1260, 1265-66, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992); *In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959) (holding the suggested combination of references improper under section 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate.").

For these reasons alone, Applicants respectfully request this rejection be withdrawn.

Additionally, even if the Examiner has established that the claimed invention is obvious, which he has not, an Applicant can rebut a *prima facie* case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. See M.P.E.P. § 716.02(a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness." *In re Corkill*, 711 F. 2d 1496, 226 U.S.P.Q. 1005 (Fed. Cir. 1985). Accordingly, in order to advance prosecution, Applicants submit an article titled, "The Development of Radiopaque Nitinol," written by John F. Boylan (" the Boylan article"), one of the inventors of the present application. Applicants submit that this article provides evidence that establishes that the claimed embolic filter system comprising a strut assembly which includes a nickel-titanium alloy and a ternary element, as recited in, for example, claim 1, is unexpectedly superior as compared with the Nitinol struts disclosed in Tsugita.

Nitinol has many attractive properties which makes it useful for human implant application. See Boylan article at page 2. Nitinol's superelastic mechanical properties

are outstanding for the demanding kinetic environment experienced by vascular stents. *See id.* Moreover, the supple responsiveness of superelastic Nitinol allows a stent to recover from compressive or impact loads in superficial arteries, for example the carotid artery. *See id.* However, both nickel and titanium, and therefore Nitinol, have intrinsically poor radiopacity. *See id.*

In an effort to improve the radiopacity of Nitinol while still retaining its superelastic properties, Boylan investigated adding a ternary element to a nickel-titanium alloy. Surprisingly, as shown in Fig. 3, Boylan found that a nickel-titanium-palladium and a nickel-titanium-platinum alloy are radiopaque and exhibit improved superelastic properties as compared to Nitinol, which is the material used in the strut assembly in Tsugita. *See id.* at page 4. Moreover, as shown in Fig. 6, the nickel-titanium-platinum alloy has exceptionally superior superelastic properties over that of conventional binary Nitinol. *See id.* at page 6. Most notably and advantageously, Boylan found that the ternary alloy has significantly less mechanical hysteresis than that of binary Nitinol. *See id.* at page 4. Less difference between the upper plateau stress, or loading stress, and the lower plateau stress, or unloading stress, means that, for example, once a stent has been designed to provide a desired outward force upon an implant (the unloading stress), the forces to collapse and contain the stent in the delivery system is significantly reduced. *See id.* A reduced collapsing force means a lighter, more flexible delivery system. *Id.* Thus, based on the results discussed in the Boylan article, it is clear that a strut assembly of the claimed invention which includes a nickel-titanium alloy and a ternary element has unexpectedly improved superelastic properties as compared to Nitinol struts disclosed in Tsugita.

For at least the foregoing reasons, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness based on Tsugita and Mitose. Moreover, even if the Examiner has established that the claimed invention is obvious, Applicants have presented sufficient evidence to rebut any *prima facie* showing. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. Claims 3 and 5

The Examiner also rejects claims 3 and 5 as being unpatentable over Tsugita in view of Mitose and further in view of U.S. Patent No. 5,713,853 to Clark et al. ("Clark"). Office Action, pages 4-5. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

As discussed above, the Examiner has failed to show that Tsugita or Mitose provide any reason why one of ordinary skill in the art would have combined the elements in the manner claimed. Furthermore, as in the previous Action, the Examiner merely relies on Clark for its teachings that "a shaft can be cut with a laser (see column 11, lines 25-26) to form the desired structure, with accuracy." See *id.*, page 4. Therefore, Clark does not remedy the deficiencies of Tsugita and Mitose. In fact, because Clark is not concerned with superelastic materials it never mentions a stress hysteresis, and certainly does not teach how to reduce a stress hysteresis, as claimed. Accordingly, this combination of references does not establish a *prima facie* case of obviousness of claims 3 and 5.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

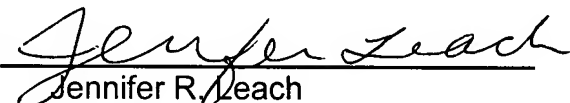
If the Examiner believes a telephone conference would be useful in resolving any outstanding issues, he is invited to call the Applicants' undersigned representative at (202) 408-4325.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: August 15, 2007

By: 
Jennifer R. Leach
Reg. No. 54,257

Attachments:

Boylan, John F., "The Development of Radiopaque Nitinol," Guidant Corporation, Endovascular Solutions, Temecula, CA, pp. 1-6.